In Paper No. 13, and in the prior Office Action, the Examiner's argument distills as follows:

(i) Collins discloses all elements of the invention, with the exception of an hydroxylated oil;

(ii) Woods discloses an emulsion containing an hydroxylated oil; and

(iii) "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose (see *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1080)." See Paper No. 8 at 3.

Further, the Examiner rejects applicants' previous arguments arguing in Paper No. 13 that "the amount of drug would not impart patentability." Paper No. 13 at 4. The applicants respectfully traverse the rejection.

The Examiner has simply not met the requirements for a *prima facie* case of obviousness because (1) the Woods/Collins combination omits two elements of the invention as claimed.

First, neither Woods nor Collins teaches an oil-in-water emulsion. Woods teaches only use of a generic emulsion; use of a specific emulsion, such as an oil-in-water emulsion, is neither taught nor suggested. In fact, Collins merely states that the Collins composition (a controlled release polymer and a proteinaceous IL-1 inhibitor) "may be stored in a sterile vial as a solution, suspension, gel, emulsion, solid, or a dehydrated or lyophilized powder."

Similarly, Woods makes no disclosure of an oil-in-water emulsion into which the COX-2 inhibitor can be incorporated. Woods teaches that the specific COX-2 inhibitor disclosed in Woods can be incorporated into a pharmaceutical composition such as "a solution, dispersion, suspension, or emulsion as well as sterile powders."

Additionally, the Collins-Woods combination does not teach or suggest a pharmaceutical composition comprising an oil and water emulsion and a drug, where more than 50% of the drug on a weight basis is dissolved in the oil phase of the emulsion. This recitation is not, as the Examiner seems to believe, a recitation of the amount of drug, but rather is a recitation of the physical structure of the pharmaceutical composition, i.e., the arrangement of the component parts of the composition. Neither Woods nor Collins discloses, teaches or suggests or even addresses obliquely an oil in water emulsion containing a drug dissolved therein, wherein more than 50% of the drug on a weight basis is dissolved in the oil phase of the emulsion.

Accordingly, because the Woods-Collins combination is missing at least two elements of the invention as claimed, the Examiner has failed to meet the requirements for a *prima facie* case of obviousness.

Even if these two elements were present, which they are not, the Examiner has failed to meet her burden of showing that a person of skill in the art would have been motivated to make the Woods-Collins combination as suggested by the Examiner, nor has she demonstrated that the person would have had a reasonable expectation that such combination would be successful. In particular, the applicants note that, in Paper No. 13 there is no reasoning provided as to motivation or reasonable expectation of success at all. Thus, the argument presented below addresses the Examiner's argument put forth in Paper No. 8.

Citing *In re Kerkhoven*, the Examiner argued that it would have been obvious to combine "two compositions" taught in the prior art to be "useful for the same purpose, in order to form a third composition to be used for the very same purpose." This reasoning is wholly inapplicable in the present case. In *Kerkhoven*, two separate groups of claims were at issue (the Board considered claims 14 and 5 to be representative of each group). The Board found that claim 14, reciting a process for preparing a spray dried detergent containing detergent A and detergent B was obvious when the prior art combination expressly disclosed both (1) the process, (2) and each of the detergents. Claim 14, the Board reasoned, merely required the mixing of a known detergent A with a known detergent B by the known process. The present invention does not recite a composition containing the Woods composition and the Collins composition in a mixture together. Thus, the holding in *In re Kerkhovan* is inapplicable in the present case and cannot properly be the basis of an obviousness rejection.

To the contrary, a person of skill would have had no motivation to make the Collins-Woods combination as suggested by the Examiner, nor is there any suggestion that such combination would give rise to successful results. Neither Collins nor Woods discloses use of oil-in-water emulsions suitable for compositions for nasal administration. Collins discloses preparations that may contain anti-inflammatory compounds for oral or injectable administration. Col. 34, line 30 to Col. 35, line 30. Similarly, Woods describes oral formulations. Accordingly, a person seeking to make an oil-in-water emulsion pharmaceutical composition suitable for nasal administration would not have sought out the teachings of either Collins or Woods and combined them to arrive at the present invention nor would he have reasonably expected such combination

to produce a successful oil-in-water emulsion as it is well known in the art that suitable vehicles for oil administration are not necessarily effective if applied to compositions for nasal administration.

Accordingly, it is respectfully requested that the Examiner reconsider and withdraw the § 103(a) rejection.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the Examiner has failed to make a *prima facie* case of obviousness based upon the cited references. Consequently, reconsideration and allowance of claims 1-7, 9-11, are earnestly solicited at the Examiner's earliest convenience.

Respectfully submitted,

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